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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<p>In re Application of</p> <p>Paul J. Carter et al.</p> <p>Serial No.: To Be Assigned</p> <p>Filed: December 7, 2001</p> <p>For: A METHOD FOR MAKING HETEROMULTIMERIC POLYPEPTIDES</p>	<p>Group Art Unit: To Be Assigned</p> <p>Examiner: To Be Assigned</p> <div data-bbox="812 525 1412 798"> <p>CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated below and is addressed to: U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202.</p> <p>Express Mail Label No. <u>EL 872 101 782 US</u></p> <p>December <u>7</u>, 2001</p> <p><i>Anna Kan</i></p> <p>Anna Kan</p> </div>
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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☒ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); or
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, or
- before the mailing of the first Office action on the merits; or
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☐ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in 37 CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior applications Serial No. 08/399,106, filed March 1, 1995 and Serial No. 08/974,183 filed November 19, 1997 and relied upon in this application for an earlier filing date under 35 USC §120.

☐ **BLAST results enclosed:**

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-Q" (nucleotide) and "BLAST Results B-1 - B-Q" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,

GENENTECH, INC.

Date: December 7, 2001

By:

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PATENT TRADEMARK OFFICE

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark OfficeAtty Docket No.
P0927C2Serial No.
To Be Assigned

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant
Carter et al.Filing Date
07 Dec 2001Group
To Be Assigned

U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
* 1	5,821,333	13.10.98	Carter et al.			03.05.95

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes No
* 2	WO 92/10209	25.06.92	PCT			

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

* 3	Ashkenazi et al., "Immunoadhesins" <u>Intern. Rev. Immunol.</u> 10:219-227 (1993)
* 4	Belshaw et al., "Rational Design of Orthogonal Receptor-Ligand Combinations" <u>Angew. Chem. Int. Ed. Engl.</u> 34(19):2129-2132 (1995)
* 5	Berg et al., "Bispecific Antibodies that Mediate Killing of Cells Infected with Human Immunodeficiency Virus of Any Strain" <u>Proc. Natl. Acad. Sci. USA</u> 88:4723-4727 (June 1991)
* 6	Brennan et al., "Preparation of bispecific antibodies by chemical recombination of monoclonal immunoglobulin G ₁ fragments" <u>Science</u> 229:81-83 (July 1985)
* 7	Chamow et al., "A Humanized, Bispecific Immunoadhesin-Antibody That Retargets CD3 ⁺ Effectors to Kill HIV-1-Infected Cells" <u>Journal of Immunology</u> 153:4268-4280 (1994)
* 8	Crick, "Is α -Keratin a Coiled Coil?" <u>Nature</u> (letter to editor) 170:882-883 (1952)
* 9	Crick, "The Packing of α -Helices: Simple Coiled-Coils" <u>Acta Crystallographica</u> 6(8-9):689-697 (1953)
*10	Dietsch et al., "Bispecific Receptor Globulins, Novel Tools for the Study of Cellular Interactions" <u>Journal of Immunological Methods</u> 162:123-132 (1993)
*11	Ellerson et al., "Isolation and Characterization of a Fragment Corresponding to the C _γ Homology Region of Human Immunoglobulin G ₁ ." <u>Journal of Immunology</u> 116(2):510-517 (February 1976)
*12	Fanger et al., "Bispecific Antibodies" <u>Critical Reviews in Immunology</u> 12(3,4):101-124 (1992)
*13	Gruber et al., "Efficient Tumor Cell Lysis Mediated by a Bispecific Single Chain Antibody Expressed in Escherichia Coli" <u>Journal of Immunology</u> 152:5368-5374 (1994)
*14	Hollenbaugh et al., "Interaction of P-Selectin (CD62) and Its Cellular Ligand: Analysis of Critical Residues" <u>Biochemistry</u> 32:2960-2966 (1993)
*15	Holliger et al., "'Diabodies': Small Bivalent and Bispecific Antibody Fragments" <u>Proc. Natl. Acad. Sci. USA</u> 90:6444-6448 (Jul 1993)
*16	John et al., "Two Pairs of Oppositely Charged Amino Acids from Jun and Fos Confer Heterodimerization to GCN4 Leucine Zipper" <u>Journal of Biological Chemistry</u> 269(23):16247-16253 (1994)
*17	Julia et al., "Rat liver alcohol dehydrogenase of class III" <u>European Journal of Biochemistry</u> 172:73-83 (1988)
*18	Kostelny et al., "Formation of a Bispecific Antibody by the Use of Leucine Zippers" <u>Journal of Immunology</u> 148(5):1547-1553 (1992)

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P0927C2	Serial No. To Be Assigned
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Carter et al.	
				Filing Date 07 Dec 2001	Group To Be Assigned
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
*19	Landschulz et al., "The Leucine Zipper: A Hypothetical Structure Common to a New Class of DNA Binding Proteins" <u>Science</u> 240:1759-1764 (1988)				
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*22	McPhee et al., "Engineering Human Immunodeficiency Virus 1 Protease Heterodimers as Macromolecular Inhibitors of Viral Maturation" <u>Proc. Natl. Acad. Sci.</u> 93:11477-11481 (1996)				
*23	Milstein and Cuello, "Hybrid Hybridomas and Their Use in Immunohistochemistry" <u>Nature</u> 305:537-540 (Oct 1983)				
*24	Nolan et al., "Bifunctional antibodies: concept, production and applications" <u>Biochimica et Biophysica Acta</u> 1040:1-11 (1990)				
*25	O'Shea et al., "Mechanism of Specificity in the Fos-Jun Oncoprotein Heterodimer" <u>Cell</u> 68:699-708 (1992)				
*26	O'Shea et al., "Peptide 'Velcro': Design of a Heterodimeric Coiled Coil" <u>Current Biology</u> 3(10):658-667 (1993)				
*27	Presta et al., "The Binding Site on Human Immunoglobulin E for Its High Affinity Receptor" <u>Journal of Biological Chemistry</u> 269(42):26368-26373 (October 21, 1994)				
*28	Ridgway et al., "'Knobs-into-holes' Engineering of Antibody CH3 Domains for Heavy Chain Heterodimerization" <u>Protein Engineering</u> 9(7):617-621 (1996)				
*29	Rodrigues et al., "Engineering Fab' Fragments for Efficient F(ab) ₂ Formation in Escherichia coli and for Improved In Vivo Stability" <u>The Journal of Immunology</u> 151(12):6954-6961 (December 15, 1993)				
*30	Roit et al. <u>Immunology</u> , 3rd edition, Mosby Limited pps. 4.8 (1993)				
*31	Roitt, et al., "Antigen Receptor Molecules" <u>Immunology</u> , Mosby Limited, 4th edition pps. 4.8 (1993)				
*32	Sawa et al., "Functional domains of transcription factor hGABPβ1/E4TF1-53 required for nuclear localization and transcription activation" <u>Nucleic Acids Research</u> 24(24):4954-4961 (1996)				
*33	Shalaby et al., "Development of Humanized Bispecific Antibodies Reactive with Cytotoxic Lymphocytes and Tumor Cells Overexpressing the HER2 Protooncogene" <u>Journal of Experimental Medicine</u> 175:217-225 (Jan 1, 1992)				
*34	Songvilai et al., "Bispecific antibody: a tool for diagnosis and treatment of disease" <u>Clin. Exp. Immunol.</u> 79:315-321 (1990)				
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*36	Ward et al., "Effects of Engineering Complementary Charged Residues into the Hydrophobic Subunit Interface of Tyrosyl-tRNA Synthetase" <u>Biochemistry</u> 26(13):4131-4138 (1987)				
*37	Zhu et al., "Remodeling Domain Interfaces to Enhance Heterodimer Formation" (IN PRESS) pps. 1-31 (1997)				
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